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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,497	02/26/2004	Robert Bals	68004167.1001	4981

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BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/787,497	BALS ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 21-39* is/are pending in the application.

4a) Of the above claim(s) *29-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2 and 21-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants response of 6/20/2007 to the restriction requirement mailed 3/21/2007 electing Invention II is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Due to the amendments to the claims, the species election requirement is moot.

Claims 2 and 21-39 are pending. Claims 29-39 are withdrawn from consideration as being drawn to a non-elected invention. Claims 2 and 21-28 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as filed does provides written description only of SEQ ID NO: 1. It additionally reasonably conveys written description of fragments of SEQ ID NO: 1 that retain angiogenic activity. However, the claims broadly read on any LL-37 receptor agonist, including "derivatives", "peptidomimetics" and "mutants" of such. The specification neither defines such terms in a manner that one could determine the metes and bounds of the invention, nor is there any written description of any derivative, peptidomimetics nor mutant of SEQ ID NO: 1. Accordingly, the written description is not commensurate in scope with the claims.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the SEQ ID NO: 1 or fragments thereof, the skilled artisan cannot envision the detailed chemical structure of the encompassed LL-37 receptor agonists used in the claimed method, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only proteins comprising SEQ ID NO: 1 or a fragment thereof with angiogenic activity, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As stated above, the specification does not provide an adequate written description of the active molecules to be used in the claimed methods. Since the active agents are not described, the person of ordinary skill in the art cannot determine the metes and bounds of the claims. Merely

claiming administration of an agent having a given activity is not sufficient to set forth the metes and bounds of those agents within the scope of the claims.

Rejections over Prior Art

Prior to setting forth the prior art rejections, the following observations are made on interpretation of the claims:

LL-37 is well-known in the art, and SEQ ID NO: 1 of the instant application consists of the art-recognized sequence for such. Accordingly, art that refers to LL-37 but does not list the sequence is presumed to intend SEQ ID NO: 1.

In applying the prior art, the Examiner has interpreted any variant of LL-37 to be a "derivative", "peptidomimetic" or "mutant".

As the claims do not specify that the patient being treated suffer from any particular medical condition, it is presumed that administration of a pharmaceutically acceptable amount of LL-37 will inherently increase angiogenesis, that property being an inseparable feature of the peptide itself.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2 and 22-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Larrick et al., U.S. Patent No. 5,618,675.

Larric et al. teach LL-37, which they designate the «"RNIP fragment of the CAP18 molecule". At column 6 lines 43+, Larric et al. teach the use of polypeptides "which comprise at least the active portion of the RNIP fragment of the CAP18 molecule and those which comprise substantially the entire CAP18 molecule." At column 7, they define the RNIP fragment as amino acids 137-170 of SEQ ID NO: 2, which is identical in sequence and length to SEQ ID NO: 1 of the instant application. They further teach substitution of amino acids in RNIP with, for example corresponding amino acids from the rabbit homologue (col. 7, lines 13-17). At the paragraph bridging columns 9-10, Larric et al. teach that the polypeptides may be used "to attenuate, inhibit or prevent LPS-associated conditions, such as Gram-negative sepsis, autoimmune disorders, inflammation and the like." Accordingly, the claims, in view of the above claim interpretation comments, are anticipated by Larric et al.

Claims 22 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirata, U.S. Patent No. 6,040,291.

Hirada teaches numerous fragments of SEQ ID NO: 1 of the instant specification, which fragments are stated to have antimicrobial activity: see column 16, Table 1 for example. The claims are drawn to bacterial-infection treating compositions comprising such peptides (claims 7, 8) and methods of treatment of bacterial infection or endotoxin shock using such peptides (claims 13, 14). Accordingly, the claims, in view of the above claim interpretation comments, are anticipated by Hirada.

Claims 2, 21-24 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Chertov et al., U.S. Patent Application Publication No. 2002/0072495.

Chertov et al. teach the use of LL-37 for boosting the immune response to conditions such as bacterial infection, viral infection and cancer; see paragraph [0027]. At paragraph [0029], dosages consistent with those in the instant specification are discussed. Claims 1-6 are drawn to a method of enhancing an immune response in subject, comprising administration of

LL-37. Accordingly, the claims, in view of the above claim interpretation comments, are anticipated by Chertov et al.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lehrer et al., Curr. Opin. Hematol. 9:18-22, teaches that LL-37 is chemotactic for human neutrophils, monocytes and lymphocytes, and that hCAP-18 is induced after injury, such as incision.

Conclusion

No claim is allowed.

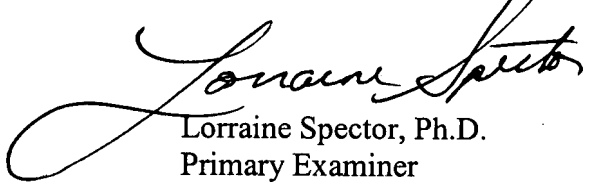
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Dr. Manjunath Rao, at telephone number 571-272-0939.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorraine Spector, Ph.D.
Primary Examiner